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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/997,792

11/30/2001

Ronald Norbert Hermeling

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6117

25885

7590

05/29/2002

ELI LILLY AND COMPANY
PATENT DIVISION
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EXAMINER

RUSSEL, JEFFREY E

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 05/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,792

Applicant(s)

HERMELING ET AL.

Examiner

Jeffrey E. Russel

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 0201.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 26-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 6) ☐ Other:

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1. The claims numbered 80 through 85 in the preliminary amendment filed November 30, 2001 have been re-numbered 26 through 31, respectively, under 37 CFR 1.126 because only 25 claims were contained in the application as originally-filed. The dependencies of the claims contained in the preliminary amendment have been changed accordingly. Any future reference to the claims will use their re-numbered claim numbers.
2. The Sequence Listing filed November 30, 2001 has been approved by STIC for matters of form.
3. The disclosure is objected to because of the following informalities: While 29 amino acid sequences are listed in the sequence listing submitted November 30, 2001, only four sequences are identified by SEQ ID NO in the specification. The remaining 25 amino acid sequences in the specification need to be identified by SEQ ID NO so that there is clear correspondence between the amino acid sequences in the specification and every amino acid sequence recited in the sequence listing. Appropriate correction is required.
4. The claim for priority contained in the preliminary amendment filed November 30, 2001 is objected to because it implies that the instant application directly claims priority based upon the provisional application even though there is no copendency between the two applications, and because priority is claimed based upon the nonprovisional application using claim language under 35 U.S.C. 119(e) ("claims the benefit of") rather than under 35 U.S.C. 120 ("is a continuation of"). Further, the status of the parent nonprovisional application needs to be updated. Correction is required.
5. Claims 26-31 are objected to because of the following informalities: A SEQ ID NO must be inserted after the amino acid sequence in claim 26. See 37 CR 1.821(d). At claim 26, line 9,

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“histidine” (first occurrence) is misspelled. At claim 26, line 12, “form” should be changed to “from”. At claim 26, line 16, “Ser” should be capitalized. Appropriate correction is required.

6. Claims 26-31 would be allowable if rewritten or amended to overcome the claim objection set forth in this Office action. The prior art of record does not teach crystals of GLP-1 or of GLP-1 analogs and also comprising zinc wherein the crystals have a tetragonal flat rod shaped or plate-like morphology. The Kim et al article and the European Patent Application 619,322 (see, e.g., Example 44) show that GLP-1 crystals and GLP-1 analog crystals do not inherently have a morphology as recited in the instant claims. Further, the prior art of record does not provide any motivation or suggestion to form crystals having the claimed morphology. Note that Galloway is silent as to any characteristics, e.g., morphology, of its disclosed and/or claimed crystals. Note also that while the European Patent Application '322 teaches plate-like crystals in Example 45, this example does not form the crystals from a zinc-containing solution. The European Patent Application '322 does not disclose the morphology of crystals produced from zinc-containing solutions.

U.S. Patent No. 6,380,357, which issued from the parent application, is cited as art of interest, but does not raise any obviousness-type double patenting issues with the instant claims.


U.S. Patent No. 6,284,727 is cited as art of interest, being the equivalent of the European Patent Application 619,322, already of record.

7. The reference crossed off of the Information Disclosure Statement filed November 30, 2001 is a duplicate citation.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Christopher Low can be reached at (703) 308-2923. The fax number for Art Unit 1653 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1653

JRussel

May 28, 2002